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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/644,703

08/19/2003

Louis A. Pena

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PEACOCK MYERS, P.C.  
201 THIRD STREET, N.W.  
SUITE 1340  
ALBUQUERQUE, NM 87102

EXAMINER

DANG, IAN D

ART UNIT

PAPER NUMBER

1647

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/644,703	<b>Applicant(s)</b> PENA ET AL.	
	<b>Examiner</b> IAN DANG	<b>Art Unit</b> 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-9, 12-26, 32, 34-38 and 46-59 is/are pending in the application.
- 4a) Of the above claim(s) 1-7, 21-26 and 46-59 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 8, 9, 12-20, 32 and 34-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/08/2007</u> .  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/26/2007 has been entered.

### **Election/Restrictions**

Applicants have elected SEQ ID NO:6 with traverse in the communication filed on 04/07/2008 is acknowledged. The traversal is on the ground(s) i) there is no undue burden to search all peptides X as amino acids sequences SEQ ID NO: 6-21 and ii) the sequences are not distinct, since they bind to their cognate receptor. This is not found persuasive for the following reasons:

Applicants' arguments have been considered but are not found persuasive. Each of the following sequences, SEQ ID NO:6-21, is a unique amino acid sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

Furthermore, although each of the sequences represents a peptide binding to heparin-binding growth factor receptor, each member of that class has unique and diverse functional features. Therefore, the only common feature of the recited SEQ ID NOs is a general secondary structure resemblance, which is not a basis upon which to base a search and examination of the claims.

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The requirement is still deemed proper and is therefore made FINAL.

***Status of Application, Amendments and/or Claims***

The amendment of 14 December 2007 has been entered in full. Claims 10-11, 27-31, 33, and 39-45 have been cancelled. Claims 8, -15, 19-20, 34-38 have been amended. Claims 1-7 and 46-59 drawn to a non-elected invention have been withdrawn.

Claims 8, 9, 12-20, 32, 34-38 are under examination.

***Specification***

The disclosure is objected to because of the following informalities:

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code (see page 12, line 8). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Appropriate correction is required.

**Rejections Withdrawn**

***35 USC § 112, First paragraph (Written Description)***

Applicant's response and arguments filed on 12/14/2007 have overcome the rejection of claims 8-20 and 27-45 under 35 USC 112, First paragraph (Written Description). The rejection of claims 8-20 and 27-45 under 35 USC 112, First paragraph (Written Description) has been withdrawn.

***35 USC § 112, First paragraph (Written Description)***

Applicant's response and arguments filed on 12/14/2007 have overcome the rejection of

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claims 8-20 and 27-45 under 35 USC 112, First paragraph (Enablement). The rejection of claims 8-20 and 27-45 under 35 USC 112, First paragraph (Enablement) has been withdrawn.

### **New Ground of Rejection**

#### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 8, 9, 12-20, 32, 34-38 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 7,166,574.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are both drawn to a synthetic heparin-binding growth factor (HGBF) analog.

Although the synthetic heparin-binding growth factor (HBGF) of the US Patent 7,166,574 has the formula I and the one the instant application has the formula II, both formulas have almost identical structural feature which includes the same spatial orientation for the X, Y, Z, J1, and J2 components for the heparin binding growth factor analog. In addition, the sequences for

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the peptides X, Y, and Z of the US patent are identical to that of the instant application and the amino acid residues for the J1 and J2 are also identical to that of the instant application. For instance the peptide sequence X consisting of SEQ ID NO:3 (YRSRKYSSWYVALKR) in claim 1 of the US Patent 7,166,574 has 100% sequence identity to the peptide sequence X consisting of SEQ ID NO:6 (YRSRKYSSWYVALKR) of the instant application. In addition, the non-signaling peptide Z comprising SEQ ID NO:2 (RKRKLERAIR) has 100% sequence identity to the non-signaling peptide Z comprising SEQ ID NO:2 (RKRKLERAIR) of the instant application. In addition, the Y that is an aminohexanoic acid tripeptide disclosed in claim 8 of the US Patent 7,166,574 is identical to the Y linker that is a three amino hexanoic acid residues recited in claim 8 of the instant application. Moreover, the J1 of the US patent 7,166,574 represents an amino acid and J2 represents a diamino acid (see claim 1 of 7,166,574) corresponding to claim 8 of the instant application reciting that J1 is a trifunctional alpha amino acid residue and claim 15 of the instant application reciting that J2 is a diamine amino acid.

Furthermore, the functional activity of HBGF analog of the US Patent 7,166,574 is the same as the one disclosed in the instant application. For instance, claim 3 of the US Patent 7,166,574 recites that binding of the HBGF analog to the heparin-binding growth factor receptor initiates a signal by the heparin-binding growth factor receptor corresponding to claim 13 of the instant application. In addition, claim 4 of the US Patent 7,166,574 recites that binding to the HBGF analog to the heparin-binding growth factor receptor blocks signaling by the heparin growth factor receptor corresponding to claim 14 of the instant application.

Therefore, the heparin-binding growth factor analog claimed in the instant application is not patentably distinct from the heparin-binding growth factor analog claimed in the US Patent 7,166,574 because they both have identical structural and functional characteristics.

## **Rejection Maintained**

### **Claim Rejections - 35 USC § 112, Second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Although Applicants have overcome the rejection of claims 8-20 and 27-45 by amending claims 8 and 11 regarding the recitation of atoms, claims 35 and 36 are now rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 35 and 36 are indefinite because it is unclear as to what the recitation of "biological response" in claims 35 and 36 is intended to encompass.

## **Conclusion**

No claim is allowed.

## **Information**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IAN DANG whose telephone number is (571)272-5014. The examiner can normally be reached on Monday-Friday from 9am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ian Dang  
Patent Examiner  
Art Unit 1647  
June 3, 2008

/David S Romeo/  
Primary Examiner, Art Unit 1647